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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,268	09/29/2003	Michael Fantuzzi	33503/US	3101

7590 03/11/2005

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EXAMINER

KOSSON, ROSANNE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/674,268

Applicant(s)

FANTUZZI, MICHAEL

Examiner

Rosanne Kosson

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-15, 17-20, 22 and 23 is/are rejected.
- 7) ☒ Claim(s) 3, 16 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/27/03, 6/7/04, 7/13/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-10 in the reply filed on February 7, 2005 is acknowledged.

The remaining claims of Groups II-IV, claims 11-13, as well as the claims of Groups V and VI, claims 14-20 and 22-24, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Claim 21 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Accordingly, claims 1-20 and 22-24 are examined on the merits herewith.

### ***Allowable Subject Matter***

Claims 3, 16 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dissolving coenzyme Q-10 (hereinafter referred to as coQ) in limonene, does not reasonably provide enablement for dissolving coQ in any monoterpene solvent or in perillyl alcohol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Specifically, claim 1 recites a composition comprising a sufficient quantity of a monoterpene suitable to solubilize coQ, and claims 4 recites that the monoterpene is perillyl alcohol. Claim 14 recites a soft gelatin capsule comprising coQ solubilized in a monoterpene, and claim 17 recites that the monoterpene is perillyl alcohol. Claim 22 recites a packaged nutraceutical comprising coQ solubilized in a monoterpene.

Instant claims 1, 14 and 22 read on dissolving coQ in any monoterpene. As noted in the specification (see p. 5, paragraph 23), monoterpenes include compounds with varying structures and solubility properties. For example, the compounds limonene, pinene, nerol, menthane, safrol and geraniol each have different properties as solvents, as shown by solubility data from the CRC (see enclosed pages from the Table of physical constants of organic compounds, CRC Handbook of Chemistry and Physics, 51<sup>st</sup> Ed., R.C. Weast, ed., The Chemical Rubber Co., Cleveland, 1970, pp. C-309, 356, 364, 392, 434 and 488). Instant claims 4 and 17 read on dissolving coQ in perillyl alcohol. Instant claims 3, 16 and 24 read on dissolving coQ in a limonene derivative. Apart from limonene, the specification provides no indication as to which monoterpenes coQ is soluble in or the range of solubility- or any quantitative solubility

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data- for any one solvent. Thus, Applicant has not demonstrated that coQ is soluble in any monoterpene but limonene. As a result, the scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to determine which monoterpenes may be used to dissolve limonene.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary (immense, because Applicants have provided no information for dissolving coQ in any monoterpene solvent but limonene), (2) the amount or direction or guidance presented (none, apart from examples with limonene), (3) the presence or absence of working examples (none with respect to any monoterpene but limonene), (4) the nature of the invention (the solvent properties of monoterpenes apart from limonene have not been demonstrated), (5) the state of the

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prior art (no monoterpenes that dissolve coQ are known), (6) the relative skill of those in the art (very high, that of highly trained research scientist), (7) the predictability or unpredictability of the art (zero because the behavior of untested materials is inherently unpredictable), and (8) the breadth of the claims (broad, as discussed above).

Accordingly, claims 1-20 and 22-24 fail to satisfy the enablement requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

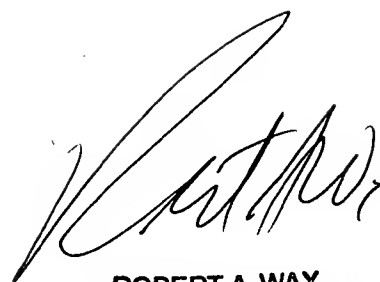
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner  
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2005-03-02

A handwritten signature in black ink, appearing to read 'Robert A. Wax', written in a cursive style.

**ROBERT A. WAX**  
**PRIMARY EXAMINER**

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